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ELG Docket No. ILL08-027-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Anthony J. McHugh	Examiner:	Sharmila S. Gollamudi
Serial No.:	09/733,640		
Filing Date:	December 8, 2000	Group Art Unit:	1616
Title:	CRYSTALLIZABLE/NON-CRYSTALLIZABLE POLYMER COMPOSITES		

TRANSMITTAL AND CERTIFICATE OF MAILING UNDER 37 CFR 1.8

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on

March 16, 2006
Date

Jonathan P. Taylor, Ph.D., Registration No. 48,338
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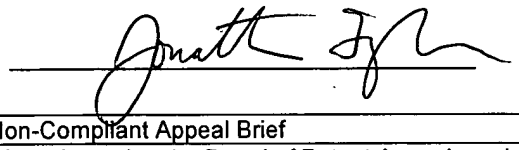

1.	Response to Notification of Non-Compliant Appeal Brief
2.	Applicant's Brief in Support of the Appeal to the Board of Patent Appeals and Interferences (amended, in triplicate)

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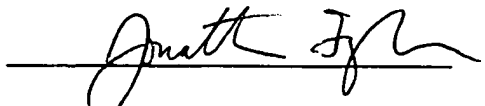

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RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF

M.S. – Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notification of Non-Compliant Appeal Brief dated March 8, 2006, Applicants submit an amended Applicant's Brief in Support of the Appeal to the Board of Patent Appeals and Interferences that now includes the Evidence Appendix and the Related Proceedings Appendix (in triplicate).

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor/s:	Anthony J. McHugh, et al.
Serial No.:	09/733,640
Filing Date:	December 8, 2000
Title:	Crystallizable/Non-Crystallizable Polymer Composites
Examiner:	Sharmila S. Gollamudi
Group Art Unit:	1616

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICANT'S BRIEF IN SUPPORT OF THE APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

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I. REAL PARTY IN INTEREST

The real party in interest is the Board of Trustees of the University of Illinois.

II. RELATED APPEALS AND INTERFERENCES

There are no other related appeals or interferences.

III. STATUS OF CLAIMS

All of the pending claims, claims 1, 3-8, 17-19, 34, 38 and 49-72 have been finally rejected and are appealed. Claims 2, 9-16, 20-33, 35-37, and 39-48 were previously cancelled.

IV. STATUS OF AMENDMENTS

Applicants filed an amendment to the claims on March 18, 2005. No amendments have been filed subsequent to the final rejection, which was mailed on June 9, 2005.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 provides an injectable composition for the controlled release of a bioactive agent. Specification, page 16, lines 14-17 and page 17, lines 15-28. The composition includes a biodegradable crystallizable polymer, a

biodegradable amorphous polymer, a biocompatible solvent and a bioactive agent. Specification, page 3, lines 27-30 and page 5, lines 1-3, 19-20. The biocompatible solvent has a miscibility with water of less than 7 percent by weight. Specification, page 5, lines 23-25.

Independent claim 34 provides a method of administering a bioactive agent, including inserting an injectable composition for the controlled release of a bioactive agent into an organism. Specification, page 16, lines 14-17 and page 17, lines 15-28. The composition includes a biodegradable crystallizable polymer, a biodegradable amorphous polymer, a biocompatible solvent, and a bioactive agent. Specification, page 3, lines 27-30 and page 5, lines 1-3, 19-20. The biocompatible solvent has a miscibility with water of less than 7 percent by weight. Specification, page 5, lines 23-25.

Independent claim 38 provides a method of making an injectable composition for administering a bioactive agent. Specification, page 16, lines 14-17 and page 17, lines 15-28. The method includes combining ingredients, where the ingredients include a biodegradable crystallizable polymer, a biodegradable amorphous polymer, a biocompatible solvent, and a bioactive agent. Specification, page 3, lines 27-30 and page 5, lines 1-3, 19-20. The biocompatible solvent has a miscibility with water of less than 7 percent by weight. Specification, page 5, lines 23-25.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues to be decided on this appeal are as follows:

Whether claims 1, 5-7, 17, 18, 34, 38, 48, 51-53, 55, 56, 58-60, 66 and 67 are anticipated under 35 U.S.C. § 102(b) over U.S. Patent No. 5,525,646 to Lundgren et al. (*Lundgren*).

Whether claims 1, 3, 5-7, 17-18, 34, 38, 49, 51-53, 55, 56 and 58-72 are obvious under 35 U.S.C. § 103(a) over U.S. Patent No. 6,432,438 to Shukla (*Shukla*) in view of *Lundgren*.

Whether claims 1, 3-19, 34, 38 and 49-72 are obvious under 35 U.S.C. § 103(a) over U.S. Patent No. 6,130,200 to Brodbeck et al. (*Brodbeck*) in view of *Lundgren*; or whether claims 3-4, 8, 19, 49, 50, 54, 57, 59, 61-65 and 68-72 are obvious over the reverse combination, that is *Lundgren* in view of *Brodbeck*.

Whether claims 1, 3, 5, 34, 38, 49, 51 and 58-72 are obvious under 35 U.S.C. § 103(a) over *Shukla* in view of PCT Application Publication No. WO 88/07366 to Bateman et al. (*Bateman*).

Whether claim 66 is indefinite under 35 U.S.C. § 112, second paragraph.

VII. ARGUMENT

The Examiner has failed to give the term "injectable" in the present claims proper meaning. In particular, the claimed invention is directed to injectable compositions for controlled release of a bioactive agent, and to methods of making such compositions and of administering bioactive agents using such compositions. The Examiner has improperly characterized the term "injectable" as merely a statement of intended use having no patentable weight. In addition, the Examiner has improperly interpreted the term "injectable" with a definition unrelated to the subject matter of the present application.

An injectable composition for administration of a bioactive agent is described in the specification as a "fluid mixture" that "transforms into a depot upon contact with the native fluid in the body" when injected into a patient. Specification, page 16, lines 20-21. The resulting depot is less fluid than the injectable composition and is phase separated from physiological fluid with which it may be in contact. Specification, page 16, lines 22-26. These injectable compositions undergo a phase transformation upon injection to form an implant for controlled release of a bioactive agent. This is in contrast to pre-formed surgical implants and to tablets or capsules for oral delivery, which are fully formed prior to administration to a patient.

A. *Lundgren* Does Not Disclose Or Suggest, But Teaches Away From, An Injectable Composition.

Independent claims 1, 34 and 38 of the present invention each specify an injectable composition for administration or controlled release of a bioactive agent. When the term "injectable" is properly considered, the anticipation rejection under *Lundgren* must be withdrawn, because *Lundgren* discloses dimensionally stable compositions. Moreover, since *Lundgren* teaches away from injectable compositions, the obviousness rejections based on *Lundgren* must also be withdrawn.

Lundgren discloses biodegradable compositions for use in tissue regeneration, where the composition is both malleable and dimensionally stable. *Lundgren*, col. 4, lines 60-67. The reference describes a malleable composition as having a shape that "can be adapted to the shape of the region to be covered, often in a three-dimensional fashion." *Lundgren*, col. 1, lines 33-44. The reference describes a dimensionally stable material as having a shape that "can be maintained over a certain period of time." *Lundgren*, col. 1, lines 45-51. Administration of the compositions involves forming the composition into the desired shape, and surgically inserting the shaped composition into the patient. *Lundgren*, col. 5, lines 6-14 and col. 10, lines 34-44. *Lundgren* teaches that the mechanical properties of malleability and dimensionally stability are a requirement for the compositions to be used for tissue regeneration, and that dimensional

stability is important for the duration of the healing process. *Lundgren,* col. 1, lines 27-32 and 45-51. There is no description that the compositions can be injected.

Lundgren fails to disclose or suggest an injectable composition for administration or controlled release of a bioactive agent. Moreover, *Lundgren* teaches away from the injectable composition specified in the claims, stating that compositions lacking dimensional stability are unsatisfactory for tissue regeneration.

1. The Examiner's failure to properly consider the term "injectable" has resulted in an erroneous rejection.

In maintaining the rejection of independent claims 1 and 38 over *Lundgren*, the Examiner has asserted that the term "injectable" is merely a statement of intended use of the composition or a statement of purpose of the process of making the composition. The reasoning presented in the Final Office Action is as follows:

> ... a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. [emphasis in original]

This statement is inconsistent with the guidelines set forth in MPEP 2111.02, which states:

> During examination, statements in the preamble reciting the purpose or intended use must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art. If so, the recitation serves to limit the claim. [emphasis added]

Thus, the Examiner's assertion that the preamble recites a purpose or intended use should be the beginning of an analysis of the preamble language, rather than a reason to ignore a term in the preamble.

An injectable composition as specified in the claims has a viscosity low enough to provide for flow through a needle, preferably an 18-20 gauge needle. Specification, page 16, lines 14-19. The claimed composition is structurally different from the compositions of *Lundgren*, which have a viscosity high enough to be dimensionally stable. The claimed method of making the composition is different from the method of *Lundgren*, as the identity and ratios of the claimed ingredients are selected so as to form a lower viscosity composition. The Examiner has attempted to correlate a polymer solution disclosed in *Lundgren* with the claimed injectable composition; however, this polymer solution is only an intermediate for the formation of a malleable and dimensionally stable film and is not used for administration or controlled release of a bioactive agent.

Lundgren, col. 5, lines 62-66; col. 9, lines 3-16. Thus, the term "injectable" in the preamble of claims 1 and 38 must be given full consideration.

Independent claim 34 recites the term "injectable composition" in the body of the claim. In maintaining the rejection of claim 34 over *Lundgren*, the Examiner has incorrectly defined the term "injectable". Claims are to be given their broadest reasonable interpretation as they would be understood by one of ordinary skill in the art that is consistent with the specification. MPEP 2111.01, *citing* In re Marosi, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983); MPEP 2111, *citing* In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Thus, when determining the reasonable interpretation of a claim term, there are two considerations: (1) how the term is defined by the specification and (2) what the term means to one of ordinary skill in the art.

The Examiner has failed to employ the first consideration, how the term "injectable" is defined in Applicant's specification, in interpreting the claims. Instead, the Examiner has asserted a dictionary definition of "injectable" that is not consistent with what this term means to one of ordinary skill in the art. Although the Final Office Action lists the medical definition of the term, "to force a fluid into (as for medical purposes)," the Examiner has interpreted the term with the less preferred definition, "to introduce as an element or factor in or into some situation or subject." This definition applies to the literary and conversational arts, and is completely unrelated to the field of bioactive agents.

It is highly unlikely that one of ordinary skill in the art of administration or controlled release of bioactive agents would look to this definition rather than the definition labeled "for medical purposes." Thus, one of ordinary skill in the art would not view the dimensionally stable compositions of *Lundgren* as "injectable."

When properly interpreted in view of Applicant's Specification and as understood by one of ordinary skill in the art, the term "injectable composition", as required by claims 1, 34 and 38 of the present application, excludes the dimensionally stable compositions of *Lundgren*. Thus, the reference fails to disclose or suggest every element of the claims, and the rejection under 35 U.S.C. § 102 over *Lundgren* should be withdrawn.

2. *Lundgren* teaches away from an injectable composition for administration of a bioactive agent.

The teachings of *Lundgren* cannot be combined with the teachings of either *Shukla* or *Brodbeck* to provide an injectable composition as specified in the claims. The disclosure of *Lundgren* teaches away from the use of the claimed injectable composition and from the use of injectable vehicles as disclosed in *Shukla* and in *Brodbeck*.

Shukla discloses a biodegradable vehicle for filling cavities or tissues in a patient. *Shukla*, col. 1, lines 9-14. The vehicle contains a biodegradable polymer

and a plasticizer, and can be formulated to provide a "free-flowing viscous liquid, a gel or a paste." *Shukla*, col. 3, lines 52-54 and col. 4, lines 5-9. The plasticizer component of the vehicle functions to improve the flow of the polymer, making the polymer less solid and more flexible. *Shukla*, col. 4, lines 5-39.

Brodbeck discloses a combination of a biocompatible polymer and a biocompatible solvent for controlled delivery of a beneficial agent. *Brodbeck*, col. 8, lines 36-41. The composition can be a viscous gel, and may be modified to be less viscous in order to administer the composition through a needle. *Brodbeck*, col. 9, lines 8-13.

Lundgren discloses biodegradable compositions for use in tissue regeneration, and has been described above. The reference teaches away from the injectable vehicles of *Shukla* and from the viscous gels of *Brodbeck*, stating that compositions lacking dimensional stability are unsatisfactory for tissue regeneration. *Lundgren*, col. 1, lines 27-32 and 45-51.

In the Final Office Action, the Examiner has asserted a variety of teachings and motivations from the references. Final Office Action, pp. 11-17. These alleged teachings and motivations cannot support a *prima facie* case of obviousness, since *Lundgren* teaches away from *Shukla* and *Brodbeck*. In re Grasselli, 713 F.2d, 731, 748, 218 USPQ 769, 779 (Fed. Cir. 1983). As noted in MPEP § 2145(X)(D)(2), "It is improper to combine references where the references teach away from their combination." With respect to the rejection involving *Brodbeck*, it is noted that the

order of the references in the rejection is immaterial to the analysis of whether references teach away from each other. Moreover, *Lundgren* teaches away from the claimed invention, which specifies an injectable composition. As noted in MPEP 2144.05(III), nonobviousness of a claim is evidenced by "a showing that the art, in any material respect, teaches away from the claimed invention." In re Geisler, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997). Thus, the rejections under 35 U.S.C. § 103 over *Lundgren* in view of *Shukla* and over *Lundgren* in view of *Brodbeck* should be withdrawn because a *prima facie* case of obviousness cannot be supported by the references.

B. *Shukla* and *Bateman* Cannot Be Properly Combined In A Rejection Under 35 U.S.C. § 103 Of The Claimed Injectable Composition

Independent claims 1, 34 and 38 of the present invention each specify a combination of a biodegradable crystallizable polymer, a biodegradable amorphous polymer, and a biocompatible solvent having a miscibility with water of less than 7 percent by weight. The combination of the teachings of *Bateman* and *Shukla* in an attempt to provide these claim elements would be improper, as such a combination would change the principle of operation of *Shukla*, and there would be no reasonable expectation of success in the combination.

Shukla discloses a biodegradable vehicle for filling cavities or tissues in a patient, and has been described above. The reference discloses that a solvent may

be used for combining the polymer and the plasticizer, but that this solvent is removed in order to form the final vehicle composition. *Shukla*, col. 4, line 64 through col. 5, line 13, and col. 5, lines 41-52. When the biodegradable vehicle is used for delivery of a biologically active substance, the biologically active substance is kept separate from the vehicle until just prior to the administration of the composition, in order to maintain the stability of the biologically active substance. *Shukla*, col. 2, lines 48-56; col. 6, lines 37-57; and Figure 1b.

Bateman discloses a solid tablet formulation for controlled release of an active ingredient, containing poly(vinyl alcohol) or a copolymer containing monomeric units derived from vinyl alcohol. *Bateman*, page 5, lines 14-26. The tablets are administered orally or by application to agricultural fields. *Bateman*, page 1, lines 9-17; page 19, lines 29-33; and Examples 7-9. Blends of crystalline poly(vinyl alcohol) with an amorphous poly(vinyl alcohol) or a copolymer containing monomeric units derived from vinyl alcohol can provide a range of release characteristics. *Bateman*, page 7, line 25 through page 8, line 5.

1. The combination of *Shukla* and *Bateman* would change the principle of operation of *Shukla*.

The biodegradable vehicle of *Shukla* provides for filling cavities or tissues in a patient, and is combined with a biologically active substance just prior to administration. The stabilization of the biologically active substance in a container separate from the biodegradable vehicle is critical to the successful use of the

vehicle for controlled release of the substance. In contrast, the teaching of *Bateman* regarding the use of blends of amorphous and crystallizable polymers for controlled release is limited to solid tablet formulations, in which the active ingredient must be present when the polymers are blended and pressed into a tablet. An attempt to incorporate the tablet formulations of *Bateman* into the biodegradable vehicle of *Shukla* would provide a composition containing the biologically active substance at the time the formulation was initially prepared.

In the Final Office Action, the Examiner has asserted a variety of teachings and motivations from the references. Final Office Action, pp. 7-9. These alleged teachings and motivations cannot support a *prima facie* case of obviousness, since combining the teachings of *Bateman* with the injectable vehicle of *Shukla* would change the principle of operation of *Shukla*. In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). As noted in MPEP § 2143.01, "If the proposed modification or combination of the references would change the principle of operation of the reference being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious."

2. There is no reasonable expectation of success in the combination of the references.

Even if *Shukla* and *Bateman* were improperly combined, there is no reasonable expectation of success in the combination. The biodegradable vehicle of *Shukla* is intended for controlled release within body cavities and

tissues. The vehicle is placed in a fixed position in the body and is intended to remain in place until it has degraded. In contrast, the solid tablet of *Bateman* may be used for controlled release in an organism only by introduction into the digestive track, where it will come into contact with acids, enzymes and bacteria. The contents of the tablet are constantly moving through the digestive track, and ingredients that are not absorbed by the body will be excreted within a matter of days. Moreover, solid tablets can only be used to administer bioactive agents that can maintain their therapeutic activity in the harsh acidic and/or enzymatic environments of the digestive track.

As noted in MPEP 2143, in order to establish a *prima facie* case of obviousness, a reasonable expectation of success must be found in the prior art. In re Vaeck, 947 F.2d 493, 20 USPQ2d 1442 (Fed. Cir. 1991) (A proper obviousness analysis requires consideration of "whether the prior art would also have revealed that in so making or carrying out [the claimed invention], those of ordinary skill would have a reasonable expectation of success."). MPEP 2144.08(II)(A). There is no disclosure in *Shukla* or *Bateman* that would provide one of ordinary skill in the art with a reasonable expectation of success in the combination of a viscous vehicle for body cavities with a tablet for oral administration. The rejection under 35 U.S.C. § 103 over *Shukla* in view of *Bateman* should be withdrawn because a *prima facie* case of obviousness cannot be supported by the references.

C. Claim 66 Is Not Indefinite

Claim 66 of the present invention specifies an injectable composition for controlled release of a bioactive agent, where the composition has a viscosity such that it can be dispensed through a 20 gauge needle. The viscosity limitation in this claim is a functional limitation, defining the composition by what it does, rather than by what it is. MPEP 2173.05(g). The consideration for a functional limitation with respect to 35 U.S.C § 112, second paragraph is whether definite boundaries of the claimed subject matter would be fairly conveyed to one of ordinary skill in the art.

Claim 66 sets definite boundaries on the composition by specifying the gauge needle that is used to evaluate the composition. Although Applicant's Specification does not recite a viscosity range that permits a composition to be dispensed through a 20 gauge needle, there is ample teaching of the requirements for dispensing by injection through a needle. For example, page 16, lines 14-19 describes compositions having viscosities such that the compositions "can be made to flow easily through an 18-20 gauge needle." Also page 9, lines 8-15 describes the use of emulsifying agents, component solvents or increased temperature to reduce the viscosity of the composition to improve its injectability. Moreover, a very simple test, which is quicker and easier than determining viscosity, may be used to determine if a composition meets this limitation – attempting to dispense the composition through a 20 gauge needle.

One of ordinary skill in the art would understand the boundaries of a viscosity of a composition that allows the composition to be dispensed through a 20 gauge needle. Thus, the rejection under 35 U.S.C. § 112, second paragraph should be withdrawn.

VIII. CONCLUSION

For the foregoing reasons, the claim rejections applied by the Examiner are unsustainable. Applicants respectfully request reversal of the Examiner's rejections.

Respectfully submitted,

Dated: 3-16-06

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IX. CLAIMS APPENDIX

1. (Previously presented) An injectable composition for controlled release of a bioactive agent, comprising:

a biodegradable crystallizable polymer;

a biodegradable amorphous polymer;

a biocompatible solvent having a miscibility with water less than 7 percent by weight; and

a bioactive agent.

2. Cancelled

3. (Original) The composition of claim 1, further comprising at least one biocompatible component solvent.

4. (Original) The composition of claim 1, further comprising an emulsifying agent.

5. (Original) The composition of claim 1, wherein the composition is sterile.

6. (Original) The composition of claim 1, wherein the biodegradable crystallizable polymer is a polyester.

7. (Original) The composition of claim 1, wherein the biodegradable crystallizable polymer is poly(ε-caprolactone).

8. (Original) The composition of claim 1, wherein the biocompatible solvent is ethyl benzoate.

9-16. Cancelled

17. (Previously Presented) The composition of claim 1, wherein the biodegradable amorphous polymer is a polyester.

18. (Previously Presented) The composition of claim 1, wherein the biodegradable amorphous polymer is poly(D,L-lactide).

19. (Original) The composition of claim 18, wherein the biodegradable crystallizable polymer is poly (ε-caprolactone) and the biocompatible solvent is ethyl benzoate.

20-33. Cancelled

34. (Previously Presented) A method of administering a bioactive agent, comprising:

inserting an injectable composition for controlled release of a bioactive agent into an organism,

wherein the composition comprises:

a biodegradable crystallizable polymer;

a biodegradable amorphous polymer;

a biocompatible solvent having a miscibility with water less than 7 percent by weight; and

a bioactive agent.

35-37. Cancelled

38. (Previously Presented) A method of making an injectable composition for administering a bioactive agent, comprising:

combining ingredients, wherein said ingredients comprise

a biodegradable crystallizable polymer;

a biodegradable amorphous polymer;

a biocompatible solvent having a miscibility with water less than 7 percent by weight; and

a bioactive agent.

39-48. Cancelled

49. (Previously Presented) The method of claim 34, further comprising at least one biocompatible component solvent.

50. (Previously Presented) The method of claim 34, wherein the composition further comprises an emulsifying agent.

51. (Previously Presented) The method of claim 34, wherein the composition is sterile.

52. (Previously Presented) The method of claim 34, wherein the biodegradable crystallizable polymer is a polyester.

53. (Previously Presented) The method of claim 34, wherein the biodegradable crystallizable polymer is poly (ε-caprolactone).

54. (Previously Presented) The method of claim 34, wherein the biocompatible solvent is ethyl benzoate.

55. (Previously Presented) The method of claim 34, wherein the biodegradable amorphous polymer is a polyester.

56. (Previously Presented) The method of claim 34, wherein the biodegradable amorphous polymer is poly (D,L-lactide).

57. (Previously Presented) The method of claim 56, wherein the biodegradable crystallizable polymer is poly (ε-caprolactone) and the biocompatible solvent is ethyl benzoate.

58. (Previously Presented) The composition of claim 1, wherein the composition is multi-layered.

59. (Previously Presented) The method of claim 34, wherein inserting is by injecting.

60. (Previously Presented) The composition of claim 1, wherein the biocompatible solvent is selected from the group consisting of lower alkyl esters of aryl acids, aralkyl esters of aryl acids, lower alkyl esters of citric acid, aryl ketones, aralkyl ketones, lower alkyl ketones and mixtures thereof.

61. (Previously Presented) The composition of claim 3, wherein the biocompatible component solvent is selected from the group consisting of triacetin, diacetin, tributyrin, triethyl citrate, tributyl citrate, acetyl triethyl citrate, acetyl tributyl citrate, triethylglycerides, triethyl phosphate, diethyl phthalate, diethyl tartrate, mineral oil, polybutene, silicone fluid, glylcerin, ethylene glycol, polyethylene glycol, octanol, ethyl lactate, propylene glycol, propylene carbonate, ethylene carbonate, butyrolactone, ethylene oxide, propylene oxide, N-methyl-2-pyrrolidone, 2-pyrrolidone, glycerol formal, methyl acetate, ethyl acetate, methyl ethyl ketone, dimethylformamide, dimethyl sulfoxide, tetrahydrofuran, caprolactam, decylmethylsulfoxide, oleic acid, 1-dodecylazacycloheptan-2-one and mixtures thereof.

62. (Previously Presented) The composition of claim 3, wherein the biocompatible component solvent is selected from the group consisting of triacetin, tributyl citrate, triethyl citrate, N-methyl-2-pyrrolidone and mixtures thereof.

63. (Previously Presented) The composition of claim 3, wherein the biocompatible component solvent is miscible with the biocompatible solvent and has a miscibility with water of at least 7 percent by weight.

64. (Previously Presented) The composition of claim 1, wherein the composition is a viscous gel.

65. (Previously Presented) The composition of claim 1 having a viscosity less than 100 poise.

66. (Previously Presented) The composition of claim 1, having a viscosity such that the composition can be dispensed through a 20 gauge needle.

67. (Previously Presented) The method of claim 34, wherein the biocompatible solvent is selected from the group consisting of lower alkyl esters of aryl acids, aralkyl esters of aryl acids, lower alkyl esters of citric acid, aryl ketones, aralkyl ketones, lower alkyl ketones and mixtures thereof.

68. (Previously Presented) The method of claim 49, wherein the biocompatible component solvent is selected from the group consisting of triacetin, diacetin, tributyrin, triethyl citrate, tributyl citrate, acetyl triethyl citrate, acetyl tributyl citrate, triethylglycerides, triethyl phosphate, diethyl phthalate, diethyl tartrate, mineral oil, polybutene, silicone fluid, glylcerin, ethylene glycol, polyethylene glycol, octanol, ethyl lactate, propylene glycol, propylene carbonate, ethylene carbonate, butyrolactone, ethylene oxide, propylene oxide, N-methyl-2-pyrrolidone, 2-pyrrolidone, glycerol formal, methyl acetate, ethyl acetate, methyl ethyl ketone, dimethylformamide, dimethyl sulfoxide, tetrahydrofuran, caprolactam, decylmethylsulfoxide, oleic acid, 1-dodecylazacycloheptan-2-one and mixtures thereof.

69. (Previously Presented) The method of claim 49, wherein the biocompatible component solvent is miscible with the biocompatible solvent and has a miscibility with water of at least 7 percent by weight.

70. (Previously Presented) The method of claim 34, wherein the composition is a viscous gel.

71. (Previously Presented) The method of claim 34, wherein the composition has a viscosity less than 100 poise.

72. (Previously Presented) The method of claim 34, wherein the composition has a viscosity such that inserting is through a 20 gauge needle.

X. EVIDENCE APPENDIX

None

XI. RELATED PROCEEDINGS APPENDIX

None